

### **REMARKS**

This paper is filed in response to the Office Action that issued on July 9, 2008. Claims 1-5 and 9-22 were pending in the Present Application, and each was rejected under 35 U.S.C. § 102(e) and on the grounds of nonstatutory obviousness-type double patenting. By this paper, claim 21 is cancelled without prejudice or disclaimer, claim 1 is amended, and new claim 23 is added to the Application. No new matter has been added by the claim amendments or claim addition, and support for the amendments and additions can be found in the Application as originally filed. Reconsideration of the Present Application is respectfully requested.

#### **Objection to the Drawings**

In the Office Action, the drawings were objected to as failing to comply with 37 C.F.R. § 1.84(p)(5) because they included the reference character 444, which was not mentioned in the description. By this paper, the specification has been amended in compliance with 37 C.F.R. § 1.21(b) to recite the reference character 444, as discussed further below. Accordingly, the Applicants respectfully request removal of the objection to the drawings.

#### **Objection to the Specification**

In the Office Action, the disclosure was objected to for failing to include the reference character 444 shown in the drawings. By this paper, the specification has been amended to recite the reference characters 444 and 462. No new matter has

been added by way of these amendments. The Applicants therefore respectfully request removal of the objection to the specification.

#### Claim Rejections – 35 U.S.C. § 102

Claims 1-5 and 9-22 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,779,679 to Shaw (hereinafter “Shaw”). The Applicants respectfully traverse this rejection. However, in order to expedite prosecution of the Application, claim 1 has been amended.

#### Claim 1

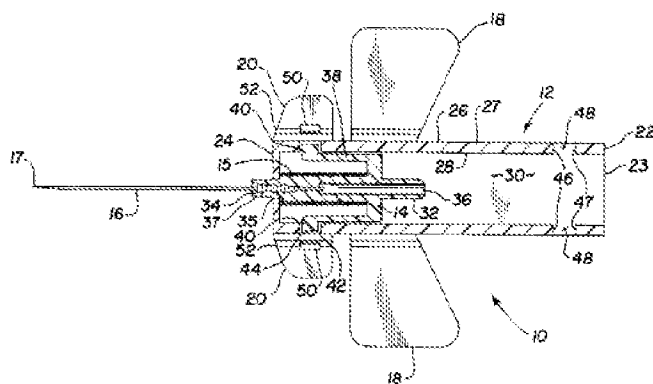
It is well settled that a claim is anticipated under 35 U.S.C. § 102(b) only if “each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” MPEP §2131, *citing Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). “The identical invention must be shown in as complete detail as is contained in the . . . claim.” *Id.*, *citing Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989).

Because Shaw does not include every element as set forth in amended claim 1, this reference cannot anticipate claim 1. For example, amended claim 1 recites a medical device that comprises, *inter alia*, a housing and

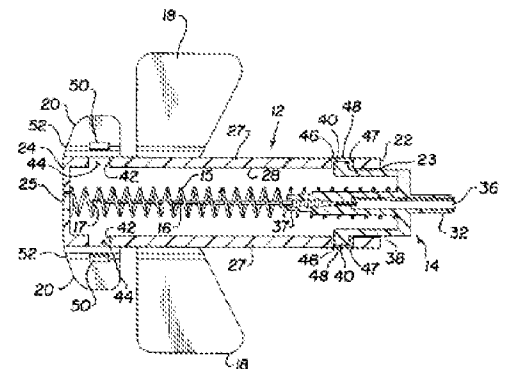
a needle hub defining a forward end and a rearward end, wherein the needle hub is displaceable between a forward position in which the first needle is in the extended position and the forward end of the needle hub is within the housing and a rearward position in which the first needle is in the retracted position, the needle hub comprising . . . an actuator . . .

configured to be outside the housing when the needle hub is in the rearward position.

In contrast to the foregoing, Shaw discloses a winged IV set 10 that includes a device body 12 and a needle holder 14, as depicted in Fig. 1 (reproduced below). The device body includes openings 44, 48. The needle holder 14 includes two opposing arms 38 and a nose 37. Each arm 38 terminates in a lug 40 that is used to position and maintain the needle holder 14 in either an extended position or a retracted position. When the needle holder 14 is in the extended position, the lugs 40 are within the openings 44 of the device body 12, and the nose 37 protrudes through an opening 25 in the front end 24 of the device body 12. As depicted in Fig. 2 (reproduced below), when the needle holder is in the retracted position, the lugs 40 are within the openings 48 of the device body 12.



**Fig. 1 of Shaw**



**Fig. 2 of Shaw**

Because the nose 37 extends through the device body when the needle holder 14 is in the extended position, Shaw fails to disclose a needle hub that is displaceable between a forward position in which a needle is in the extended position and the forward end of the needle hub is within the housing. Additionally, because the lugs 40 of the arms 38 are within the windows 48 of the device body 12 when the needle holder 14 is in the retracted position, Shaw fails to disclose an actuator that is configured to be outside the housing when the needle hub is in the rearward position.

Shaw indicates that alternative embodiments of the winged IV set 10 “may rely on a lip or constriction in opening 23 of back end 22 [of the device body 12] to retain needle holder 14 instead of openings 48.” Shaw, column 6, lines 37-40. Presumably, in such alternative embodiments, the lugs 40 would remain within the housing 40 and would thus “only act to lock needle holder 14 in the extended position, with the position after retraction being more loosely defined and maintained.” *Id.* at column 5, lines 10-13.

Shaw provides no indication that the lugs 40 would be permitted to move outside of the device body 12 in the alternative embodiments. Indeed, allowing removal of the lugs 40 from the device body 12 would permit the needle holder 14 to be completely removed from the housing. This would change the principle of operation of the winged IV set 10 and would thereby frustrate the fundamental purpose of Shaw, which is to provide for the retraction of the needle 17 so as to “significantly decrease the possibility of inadvertent needle sticks.” *Id.* at column 1, lines 7-8. Therefore, it would not be

obvious to one of ordinary skill in the art to modify the teachings of Shaw to arrive at the limitations recited in claim 1. See M.P.E.P. § 2143.01 (VI).

An arrangement such as that recited in amended claim 1 can advantageously permit for a more compact device. For example, Shaw's device can be compared with the device shown in Figs. 14A-15 of the Present Application, which is a non-limiting illustration of a device that reads on amended claim 1. The nose 37 of the needle holder 14 of Shaw extends forward from the device body 12, which has a relatively wide transverse dimension that is substantially uniform along the longitudinal length of the device body 12. In contrast, as shown in Fig. 14B of the Present Application (reproduced below), the barrel 441 of the device 410 can taper toward its forward end and can itself define a nose-like structure. The forward end of the barrel 441 can be closer to the needle 430 because the forward end of the needle tube 460 is within the barrel 441.

In view of the foregoing, the Applicants respectfully submit that amended claim 1 is patentable over Shaw. It is therefore respectfully requested that the rejection of claim 1 under 35 U.S.C. § 102(e) be withdrawn and that this claim be passed to allowance.

#### Claims 2-5 and 9-22

Each of claims 2-5 and 9-22 stands rejected under 35 U.S.C. § 102(e) as being anticipated by Shaw. Claim 21 has been cancelled, thereby mooting the rejection of this claim. Because each of claims 2-5, 9-20, and 22 includes all of the limitations of

claim 1, Shaw fails to anticipate each of claims 2-5, 9-20, and 22 for at least the reasons discussed above with respect to claim 1. Therefore, the Applicants respectfully request that the rejection of claims 2-5, 9-20, and 22 under 35 U.S.C. § 102(e) be removed and that these claims be passed to allowance.

#### New Claim 23

Claim 23 depends from claim 1 and is therefore patentable over Shaw for at least the reasons discussed above with respect to amended claim 1. The Applicants respectfully submit that new claim 23 in condition for allowance.

#### Double Patenting

Each of claims 1-5 and 9-22 stands rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,641,555. The Applicants are submitting herewith a Terminal Disclaimer to Obviate a Double Patenting Rejection Over a Prior Patent with respect to U.S. Patent No. 6,641,555, thereby mooted the double patenting rejection.

### **CONCLUSION**

In view of the foregoing amendments and remarks, the Applicants submit that the Application is condition for allowance and a Notice of Allowance is respectfully requested. Should questions exist after consideration of the foregoing, the Office is kindly requested to contact the Applicants' attorney at the address or telephone number given herein.

Dated this 9th day of October, 2008.

Respectfully submitted,

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